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No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.

On Appeal from the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE NATIONAL ASSOCIATION OF COUNTIES, INTERNATIONAL CITY MANAGEMENT ASSOCIATION, NATIONAL CONFERENCE OF STATE LEGISLATURES, NATIONAL LEAGUE OF CITIES AND U.S. CONFERENCE OF MAYORS AS *AMICI CURIE* IN SUPPORT OF APPELLANTS

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QUESTION PRESENTED

Whether regulations of the Food and Drug Administration ("FDA"), which set minimum federal standards for the collection and transportation of blood and blood products, including blood plasma, preempt Hillsborough County's Ordinances #80-11 and #80-12, which provide additional but not conflicting safety standards for the collection of blood plasma from paid donors.

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INTEREST OF *AMICI CURIAE*

Amici are organizations whose members include state, county and municipal governments and officials located throughout the United States. *Amici* and their members therefore have a vital interest in the legal issues that affect the powers and responsibilities of state and local government.

The court of appeals held that FDA regulations concerning blood plasma centers preempt two ordinances enacted by Hillsborough County, even though the federal regulations were not expressly intended to preempt local law and do not conflict with any provisions of the County ordinances. This holding involves a dramatic extension of the preemption doctrine because it sanctions *implied*

preemptions by federal agencies, not the Congress, when no conflict between federal and local law has been established. The holding thus significantly infringes on the ability of state and local governmental units to undertake concurrent and supplemental regulation on matters affecting public health and safety, an area traditionally regulated by the state's police power. *See Head v. New Mexico Board of Examiners*, 374 U.S. 424, 428 (1963); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). Unless this Court holds that, absent preemptive intent by the Congress, federal regulatory agencies must either expressly state their intention to preempt or must clearly demonstrate a conflict between federal and local law, this case will have a direct, immediate and adverse effect on matters of vital importance to *amici* and their members. *Amici* are therefore submitting this brief to assist the Court in its resolution of this action.[1]

STATEMENT

(1) The Public Health Service Act and the FDA's Regulations

In 1970, Congress amended Section 347 of the Public Health Service Act, 42 U.S.C. § 262, to include, *inter alia*, blood and blood "products" (blood components or derivatives) within the licensing authority of the (now) Department of Health and Human Services ("HHS") and its subordinate agency, the Food and Drug Administration ("FDA"). Pub. L. 85-881, § 2, 72 Stat. 1074.[2]

[1] Pursuant to Rule 36 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

[2] FDA implements Section 347 under delegated authority from the Secretary of HHS. 42 U.S.C. § 264. The FDA licensed blood preparation facilities prior to 1970, but the Fifth Circuit declared the FDA's regulation of blood banks to be beyond the agency's statutory authority. *Blank v. United States*, 400 F.2d 302 (5th Cir. 1963). Congress then amended the statute to make it clear that the FDA's licensing authority extended to blood and blood products. H.R. Rep. No. 91-1035, 91st Cong., 2d Sess. 1-3 (1970); *Communicable Disease and Immunization Programs*, Hearings before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 10-11 (1970) (remarks of Dr. Robert Marston, Director National Institute of Health).

Section 347, the single provision governing this licensing scheme, requires blood or blood components that are transported in interstate commerce to be prepared at an establishment holding a valid FDA license. 42 U.S.C. § 262(a). The licenses are to be issued upon a showing of compliance with FDA standards "designed to insure the continued safety, purity, and potency of such products. . . ." 42 U.S.C. § 262(d). FDA is authorized in its discretion to inspect such establishments for compliance with the regulatory standards. 42 U.S.C. § 262(c) and (d). The statute contains no specific requirements for receipt of a license and contains no provision concerning the relationship between this provision and state law.

The FDA has adopted regulations implementing the 1970 amendment which govern various types of blood products and blood banking activities. 21 C.F.R. 600, 601, 606, 610 and 640.[3] Standards for blood plasmapheresis —the process of removing plasma from whole blood—are set out in Subpart G of Part 640. Like the statute, these regulations are intended to ensure the quality of the blood products derived from plasma, but the regulations also set minimum standards in order to protect donors from practices that might endanger their health. *See* 39 Fed. Reg. 26161 (1974). Specifically, the regulations require that the facility obtain the donor's written informed consent (21 C.F.R. 640.61); require that a licensed physician be present and that either he or someone under his supervision, determine the donor's suitability for the proce-

[3] There are special regulations concerning plasmapheresis because donors ordinarily receive compensation for undergoing the procedure, which creates unique public health problems. *See* 39 Fed. Reg. 26161 (1974).

dure (21 C.F.R. 640.63); and, finally, require that an examining physician issue a certificate that the donor is in good health (21 C.F.R. 640.63). The regulations also prescribe a set of donor qualifications, which include normal temperature, normal pulse rate and freedom from a history of or recent contacts with hepatitis. 21 C.F.R. 640.63(c). Finally, any person who appears intoxicated or otherwise unable or unwilling to answer questions truthfully should be considered unsuitable for plasmapheresis. 21 C.F.R. 640.63(d).[4] To monitor these standards, FDA requires records to be kept on each donor. 21 C.F.R. 640.72. Nothing in the regulations or in the original statement of reasons for adopting the regulations indicates that the FDA's regulations were intended to be the maximum or exclusive requirements for plasmapheresis licensees or were otherwise intended to preempt state authority to adopt supplemental or complementary safety standards for such facilities.

(2) Hillsborough County's Ordinances

In November 1980, Hillsborough County, Florida ("County") enacted Ordinances #80-11 and #80-12,[5] which, combined with the implementing regulations adopted by the County's Health Department in March 1981,[6] broadly regulate the practices of commercial blood plasma facilities. (J.S. App. A5). Ordinance #80-11 is a licensing statute, which requires every blood plasma[7]

[4] The regulations also establish minimum standards for conducting plasmapheresis, and for processing, storing and labelling plasma units obtained during the procedure. 21 C.F.R. 640.65, 640.68 and 640.70.

[5] Both ordinances are reproduced in full at J.S. App. A29-A39.

[6] The Health Department's regulations implementing County Ordinance #80-12 are reproduced in full at J.S. App. A40-A42.

[7] Blood plasma donors are individuals who sell "the liquid portion of his or her blood (plasma), through the plasmapheresis process." (Ord. 80-12, § 3(A); J.S. App. A33). "Plasmapheresis" was defined by the district court in its findings of fact as follows: "In a single procedure this process removes whole blood from the donor,

center to pay a license tax and permits the Health Department access to the centers to inspect for violations of the County's health standards. (J.S. App. A29-A30).

Ordinance #80-12 establishes "a system for the registration . . . and the gathering of medical data applicable to" donors who give blood at centers and receive compensation. (Ordinance 80-12, § 2; J.S. App. A32). Specifically, Ordinance #80-12 creates a donor identification system requiring each person who wishes to sell plasma to obtain a donor identification card which is valid at only *one* plasmapheresis facility within the County. (Ordinance 80-12, §§ 4-5; J.S. App. A33). Each facility in the County is prohibited from performing the plasmapheresis procedure on any individual who has not presented a valid identification card for that facility. For each procedure, the facility must also fill out a form, which contains basic information about the donor and the quantity and quality of plasma sold to the facility. This information is then delivered to the County Health Department on a daily basis. (Ordinance 80-12, § 6(A), (B); J.S. App. A33-A34).

Ordinance #80-12 also requires each facility to ascertain the basic fitness of each donor to undertake the plasmapheresis procedure. The facility must determine how much blood the donor has had removed recently, make sure the donor has a certificate of good health from a physician who has personally examined him and analyze the breath of the donor with a breathalyzer to assure that his or her blood alcohol content does not exceed .07 per cent. (Ord. #80-12, §§ 6-7; J.S. App. A35-A36). Finally, the Ordinance incorporates by reference Part 640 of Title 21 of the Code of Federal Regulations—the

removes the plasma from the whole blood, and then returns the red blood cells to the donor." (J.S. App. A14). *See id.* at A3, A33). Although the ordinances refer to individuals who sell their blood to plasmapheresis centers as "vendors," we will refer to such individuals as "donors," to avoid confusion with the centers, which also sell blood plasma.

FDA's regulations "concerning plasmapheresis and source plasma (human)." (Ord. 80-12, § 15; J.S. App. A39).[6]

Ordinance #80-12 explains that the identification system was adopted because the Board of County Commissioners found "that the interests of the public health mandate the monitoring of the plasmapheresis procedure within Hillsborough County." (J.S. App. A32). In addition, the express purpose of the Ordinance "is to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma [donors] as being in the common interest of the health of the people of [the County]." (Ord. 80-12, § 2; J.S. App. A32-A33). At trial, County officials testified that the major purposes of the County's scheme are to prevent donors from the risk of overbleeding by going from one center to another (Tr. 151-152) and to make certain that donors are not so intoxicated that they cannot give an informed consent to the procedure (Tr. 149-151). Finally, the County wanted generally to prevent chronic alcoholics and individuals with hepatitis from undergoing the plasmapheresis procedure; the former because the process poses a serious health risk to the donor (Tr. 189) and the latter because the contaminated blood poses a serious health risk to employees of the plasmapheresis centers (Tr. 149).

Certain obligations imposed by the County are not contained in the FDA's regulations: (a) the County requires the centers to fill out an additional form for each procedure; (b) the County requires the donors to pay an initial fee and the centers to pay both a license tax and additional fees to cover the County's administrative ex-

[6] To cover its expenses in processing the various forms required under the scheme created by the two ordinances, the County charges a ten dollar fee for a donor identification card and a one dollar fee for each plasmapheresis procedure performed by a facility. (Ord. 80-12, §§ 5(A), 6(F); J.S. App. A33, A35).

penses; (c) the County also requires each vendor to have a center-specific identification card so that he cannot sell blood to more than one center within the County; (d) the County requires a breathalyzer test to be administered and passed before the plasmapheresis procedure can be performed; and (e) the County has its own system of inspecting the centers to ensure compliance with both the County's particular regulations and those of the FDA that have been incorporated by reference.

(3) Proceedings in the Lower Courts

Appellee, a Florida corporation which wholly owns a plasmapheresis center in Hillsborough County, filed suit in the United States District Court for the Middle District of Florida, challenging various provisions in the County's Ordinances #80-11 and #80-12, as unconstitutional under a variety of legal theories. After a bench trial, the district court upheld most of the provisions of the ordinances against all constitutional attacks (J.S. App. A13-A19), but did declare the breathalyzer requirement to be invalid as "an impermissible burden on interstate commerce" (*id.* at A19).

In upholding the rest of the provisions in the ordinances, the district court found that there was a "need for and beneficial effect of a county-wide system" of donor identification, because federal regulations contain no system to monitor "the frequency with which individual [donors] undergo the plasmapheresis procedures" (*id.* at A16). The court further found that because people are paid for selling plasma, they are relatively likely to "put themselves in real danger of being overbled" by donating too frequently at different centers. (*ibid*). Finally, the court found that "significant protection for [donors] would be assured" by the donor identification system and that "the license and plasmapheresis fees will pay for the cost of the County of implementing and enforcing the ordinances" (*id.* at A18).

The district court held that the ordinances were not preempted by federal law because there was (1) no evidence of express Congressional intent to preempt state law, (2) an insufficient indication of any implicit Congressional intent to occupy the field of blood plasma regulation and (3) no specific conflict between the ordinances' requirements and those contained in the FDA's regulations (*id.* at A17).

On cross-appeals, the court of appeals affirmed in part and reversed in part (J.S. App. A1-A12). The court of appeals held that all of the provisions in the ordinances, including the breathalyzer provision, were preempted by federal law. Like the district court, the court of appeals concluded that Congress had not expressly preempted state or local law and that the applicable regulations did not explicitly preempt local regulations (*id.* at A7). In addition, the court of appeals cited no facts of record showing that there was any specific conflict between the FDA's regulations and the ordinances. Nevertheless, applying the tests of *Pennsylvania v. Nelson*, 350 U.S. 497 (1956), the court of appeals concluded that the FDA's regulations by their scope and emphasis on uniformity implicitly occupied the field of plasmapheresis regulation and therefore even complementary local law requirements for safeguarding the health of plasma donors and center employees could not survive. The court also held that the County's ordinances would interfere with the FDA's regulatory purpose of assuring a continuing supply of healthy donors. The County then filed a jurisdictional statement and this Court noted probable jurisdiction.

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[9] The court of appeals did not declare "clearly erroneous" the district court's findings that there was no conflict between the federal and County requirements (Fed.R.Civ. P. 52(a)), and did not consider the Commerce Clause issues.

SUMMARY OF ARGUMENT

At stake in this case is the ability of state and local governments to exercise their traditional police powers to supplement minimum requirements of federal agencies by adopting non-conflicting health and safety standards that respond to local needs. This is not a case where a local government seeks to oust federal authority by adopting laws that conflict with federal law. Instead, Hillsborough County has created a local system of regulation that embraces the federal government's requirements and merely adds to them to achieve health and safety objectives that complement, and do not conflict with, the purposes of the federal regulatory regime.

(1) In *Fidelity Federal Savings & Loan Ass'n. v. De La Cuesta*, 458 U.S. 141 (1982) and *Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S.Ct. 2694 (1984), this Court required that preemptive intent of a *federal regulatory agency* be clearly established before the agency could nullify *non-conflicting* state law. Accordingly, the court of appeals erred in holding that a federal administrative agency can preempt even complementary state and local public health standards without the agency stating expressly in its regulations its intent to occupy the field of regulation.

Comity between federal and state interests requires rejection of the ruling by the court of appeals that preemption of non-conflicting state law can be implied from agency regulations alone. Under *De La Cuesta*, federal agencies have extraordinary power to oust non-conflicting state regulation whenever they do so expressly in their regulations pursuant to valid delegated authority and with an adequate statement of reasons. Requiring federal agencies to act expressly when they intend to use their preemption power over non-conflicting state law is the least that should be required under sound principles of federalism. For this Court to allow federal agencies

to preempt a field, absent express or implied congressional intent and without an express statement of agency intent, denies state and local officials a reasonable opportunity to comment and to engage the agency in a dialogue concerning whether preemption of non-conflicting state law is in the public interest. Such a holding will also create needless uncertainty for state and local agencies concerning the scope of what they can regulate, and permit private interests to challenge in federal court virtually any local attempt to supplement existing federal licensing schemes. On the other hand, a holding that agency preemption of non-conflicting state law must be expressly set forth in regulations will not preclude federal agencies from seeking to pre-empt *conflicting* state laws on a case by case basis under the agency's rulemaking or adjudicatory procedures or in a judicial proceeding.

(2) Even assuming that implied preemption is ever appropriate for agency regulations, it should only be permitted when three standards are *all* met: when the subject matter is of national concern, when the agency has exhaustively regulated the subject *and, most importantly,* when state or local regulation clearly creates a factually established conflict with the purpose or implementation of the federal regulatory scheme.

In the context of assessing the preemptive effect of an agency's regulations, the court of appeals thus erred in giving equal weight to the "three tests" in *Pennsylvania v. Nelson.* Satisfaction of the first two tests, while plainly necessary, is not at all sufficient to justify implied preemption by a federal agency, as opposed to Congress. First, exhaustive rules governing any subject within an agency's jurisdiction is the norm and not the exception for agency regulation, and therefore, the existence of a "comprehensive regulatory scheme" cannot, in and of itself, be dispositive of an agency's preemptive intent. *See New York Dep't. of Social Services v. Dublino,* 413 U.S. 405 (1973). Second, uniform, minimum standards, in

and of themselves, should not be sufficient to establish preemption by regulation because they do not imply any intention to regulate exclusively. Reliance on either of these two factors alone—or in tandem—will cause courts to find preemption where it is not necessary to achieve any federal objectives.

Implied preemption by regulation is proper only if there is a clear factual basis for a court to conclude that local standards pose a real and serious conflict with the federal regulatory scheme. Such a conflict exists when it is impossible to comply with the state law without violating federal regulations or without utterly frustrating federal regulatory objectives. In this case, the goals of both the FDA and the County are congruent, and the court of appeals does no more than assert, without any specific analysis, that the federal goal of assuring a supply of healthy donors will be impaired by the County's ordinances. Its "analysis" of the purported conflict is wholly inadequate to justify nullifying a local government's effort to protect the public health by adopting standards that complement those of the FDA.

ARGUMENT

The preemption doctrine, which is derived from the Supremacy Clause of the Constitution, has traditionally involved the issue whether *Congress* has intended in a particular statute to exercise its supreme authority to regulate exclusively—without any state or local involvement. In ascertaining Congress' preemptive intent, this Court consistently has held that preemption is "compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *Fidelity Federal Savings & Loan, Ass'n. v. De La Cuesta,* 458 U.S. at 153. In addition, preemption is required whenever state law actually conflicts with a federal statute. 458 U.S. at 153.

While the standards for judging the preemptive effect of Congress' actions are well established, the court of

appeals did not hold that Congress expressly or implicitly intended to preempt Hillsborough County's Ordinances. The court held, instead, that the FDA through its regulatory scheme impliedly preempted local law. Although this Court has had relatively few occasions to examine the preemption doctrine as it relates to agency-created law, it nevertheless has established some clear rules.

It is well settled that when state law directly conflicts with a federal regulation then the Supremacy Clause of the Constitution requires that the federal regulation must prevail, just as if it were a federal statute. *See, e.g., Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. 2694, 2703-2704 (1984); *Free v. Bland*, 369 U.S. 663, 668 (1962); *United States v. Shimer*, 367 U.S. 374, 385 (1961). It is also clear that, within its area of delegated authority, an administrative agency has power that is similar to Congress' to declare expressly a subject to be a matter of exclusive federal concern that will be governed solely by federal regulations.[10] By doing so the agency ousts all state laws, even those that may complement, rather than conflict with, federal law. *See, e.g., Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. at 2700-2703; *Fidelity Federal Savings & Loan Ass'n. v. De La Cuesta*, 458 U.S. at 154.

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[10] The powers are not identical. Congress is not obligated to provide specific reasons for its enactments, but the Administrative Procedure Act requires agencies to provide a statement of reasons to justify even informal rules. 5 U.S.C. § 553. Moreover, although the Court in *De La Cuesta* held that the agency's express decision to preempt state law is subject to the "arbitrary and capricious" standard of review applicable to other agency rules, the Court did not foreclose the possibility that action that might otherwise be permissible is arbitrary because its effect is to oust all state and local law on the subject. At a minimum, efforts to nullify state law should be subject to a searching inquiry into the agency's reasons for such an extraordinary assertion of its power. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971).

The issue posed by this case is whether, or under what circumstances, it is appropriate for a court to find that an *agency*, as opposed to Congress, has *impliedly* preempted all state law, even that which is complementary to the federal scheme. The court of appeals in effect held that the standards in *Pennsylvania v. Nelson*, used by this Court to determine whether Congress implicitly has occupied the field and preempted all state law, apply with equal force to agency action. We submit that this holding is wrong. The Eleventh Circuit's decision involves a dramatic and wholly unwarranted extension of the preemptive power of administrative agencies and therefore this Court should reaffirm and clarify its holding in *De La Cuesta* that federal agencies can preempt state laws only when their intent is expressly set forth in the agency's regulations (part I, *infra*) or when there is a clear showing of a conflict between the federal regulations and state law (part II, *infra*).

I. The Preemption Of Non-Conflicting State Law By Agency Regulation Is Appropriate Only When The Federal Agency Has Expressly Indicated In Its Regulations Its Intention To Preempt State Law.

(A) The court of appeals did not find *any* evidence of *congressional* intent, either in the relevant statutes or their legislative history, to preempt state and local regulations concerning the plasmapheresis process.[11] It did not

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[11] Nor is there any basis for such a holding. Congress made it clear in 42 U.S.C. § 263n, which is a companion provision of the Public Health Service Act that deals with federal health standards for electronic products, that it knew how to occupy the field of regulation when it felt the subject matter warranted it. That provision expressly states that no state or local government has authority to adopt any standard or to continue in effect any standard "which is not identical to the Federal Standard." 42 U.S.C. § 263n. The absence of any comparable language in 42 U.S.C. § 262, which was enacted at the same time, is compelling evidence that Congress never intended to preempt the field of biological product regulation, including the regulation of blood plasma.

find that the *congressional* scheme, which is embodied in a single, relatively short statutory provision, compelled the conclusion that Congress intended to occupy the field of plasmapheresis regulation.[12] The court of appeals did not find that local standards would undermine any *congressional* objective to assure nationwide uniformity for plasmapheresis procedures.[13] What it found instead was

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[12] The court's assertion that blood is a matter of national concern is insufficient to show any implied *congressional* intent to preempt blood plasma regulation. Every subject about which Congress legislates is by definition a matter of national concern, but that cannot mean that every piece of legislation preempts the field and ousts all state law. *See Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 447 (1960) ("The mere possession of a federal license, however, does not immunize a ship from the operation of the normal incidents of local police power. . . ."); *De Canas v. Bica*, 424 U.S. 351, 360 n.8 (1976). Instead, the Court must consider whether the subject is *uniquely* a matter of federal concern. With this standard, the Court has held that laws dealing with subversives who try to overthrow the federal government involve uniquely federal concerns. *Pennsylvania v. Nelson*, 350 U.S. 497 (1956). Similarly, the Court has held that alien registration was a matter of unique federal concern because of Congress's primary authority to regulate immigration and foreign affairs. *Hines v. Davidowitz*, 312 U.S. 52 (1941). Because it also falls within the state's traditional power to promote health and safety, the regulation of blood plasma obviously does not implicate any uniquely federal concerns comparable to those in *Hines* and *Nelson*.

[13] Blood plasma is not a subject that so obviously requires a uniform national role that a court could fairly infer that *Congress* intended to oust state and local efforts to regulate donors. The Court has found that some statutory schemes regulating trains and ships or shipping preempt state law, because commerce would be adversely affected if standards or requirements other than those imposed by federal law could be imposed by every jurisdiction in which a train or ship passed or entered. *See, e.g., Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 157-158 (1978); *Southern R. Co. v. Railroad Comm'n.*, 236 U.S. 439 (1917).

But the regulation of blood plasma at the source of its creation as a product does not create any obstacles for interstate commerce that might justify an inference that Congress would have intended the FDA's procedures to be exclusive. This is not an area of the

a substantial administrative *agency* scheme and an *agency-created* set of minimum standards for protecting donor safety. (J.S. App. A8-A9). Those findings do not, however, show Congress's intent and the court of appeals did not claim that they did. The most they logically could do is support a finding that Congress authorized the agency to exercise preemptive authority and that the *FDA* implicitly intended to occupy the field of plasmapheresis regulation. But, as we now show, this Court has required federal agencies to state "clearly" an intent to preempt, which should be read to mean that the agency must state expressly in the regulation that it intends to preempt state law.

(B) The court of appeals seems to have assumed that since "[f]ederal regulations have no less pre-emptive effect than federal statutes," *Fidelity Federal Savings & Loan Ass'n. v. De La Cuesta*, 458 U.S. at 151, the standards used to ascertain Congress' implied preemptive intent can be applied directly to agency action. But *De La Cuesta*, properly understood, stands for precisely the opposite proposition.

De La Cuesta involved the preemptive effect of a Federal Home Loan Bank Board regulation that expressly authorized federal savings and loans to include "due-on-sale" clauses in their mortages. Some states, including California, had declared such clauses illegal under state law. In disputes between a lender and a borrower in California, the California state courts had held that the state law was valid, in part, on the theory that federal regulations, in contrast to the statute pursuant to which they were promulgated, cannot preempt state law.

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law "inherently requiring national uniformity." *Head v. New Mexico Bd. of Examiners*, 374 U.S. 424, 430 (1963). There is, therefore, nothing that makes the plasmapheresis process any more suitable for exclusive federal regulation than the quality of avocadoes. Compare *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963).

This Court's statement about the preemptive effect of federal regulations was made in response to the bald holding of the California courts that agency regulations cannot preempt state law. The Court easily rejected the state courts' holding, reaffirming that the Supremacy Clause embraced federal regulations. See *United States v. Shimer*, 367 U.S. 374 (1961); *Free v. Bland*, 369 U.S. 663 (1962).

But to hold that the preemptive effect of a regulation and a statute are the same is not to say that the legal standards for finding preemption are or should be identical. Indeed, the Court implicitly recognized this point in *De La Cuesta* when it set out specifically the standards applicable to deciding when the regulations, as opposed to an Act of Congress, preempt state law. On that issue, the Court held that preemption is appropriate only if an agency "clearly" intends to preempt a specific subject, such as the availability of due-on-sale clauses in home mortgages, and if the agency was delegated adequate authority to regulate that particular subject. 457 U.S. at 154. In *De La Cuesta*, this Court focused on the *express* intent of the Federal Home Loan Bank Board to preempt all state regulation. *Ibid.* The Court conditioned its holding, that the Board's regulation ousted state law, on the existence of a clear regulatory statement that the Bank meant to eliminate all state efforts to regulate due-on-sale practices of federal savings and loans. *Id.* at 159. *De La Cuesta* thus requires a clear expression of administrative intent to preempt all state efforts, including non-conflicting laws, to regulate the same subject.

Just last Term, the Court followed precisely the same analysis in declaring Oklahoma's statutory restrictions on cable television advertising to be preempted by regulations of the Federal Communications Commission. *Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. at 2700-2703. Again the Court undertook to determine whether "the FCC has resolved to pre-empt an area of cable television regulation" (*id.* at 2701) and declared the State's provisions

invalid because they "interfered with a regulatory area that the Commission has *explicitly* pre-empted." *Id.* at 2703 (emphasis added). Thus, this Court has limited the doctrine of preemption of the field when applied to agency regulation—as opposed to congressional action—to situations where the agency expressly declares what area of regulation it intends should be off limits to any state or local activity. *See California v. Zook*, 336 U.S. 725, 737 (1949) ("one would expect the federal agency to be specific if it intended to supersede state laws").

(C) A rule limiting the authority of federal agencies to preempt nonconflicting state law to situations where preemptive intent is clearly expressed in the regulation itself is supported by sound policies.[14] To understand why a federal agency's authority should be so limited, it is important to appreciate the scope of the power granted by *De La Cuesta*. Within the confines of the power granted to them by Congress, agencies have very broad discretion to preempt state law.[15] *De La Cuesta*

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[14] Nor is a requirement of a clear statement by the federal government of its intent to intrude on traditional state authority unprecedented. This Court in other cases where federal-state relations were implicated has refused to imply that Congress, much less a federal agency, intended to invade state interests. *See, e.g., Parker v. Brown*, 317 U.S. 341, 351 (1943) ("In a dual system of government in which, under the Constitution, the states are sovereign, save only as Congress may constitutionally subtract from their authority, an unexpressed purpose to nullify a state's control . . . is not lightly to be attributed to Congress"); *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 16 (1981) ("Because such legislation imposes congressional policy on a State involuntarily, and because it often intrudes on traditional state authority, we should not quickly attribute to Congress an unstated intent to act. . . .").

[15] Although Justice O'Connor pointed out in her concurring opinion in *De la Cuesta* (458 U.S. at 172), that the delegation of authority to the Bank Board to regulate federal savings and loans "does not permit the Board to pre-empt the application of all state and local laws to such institutions," it is nevertheless clear that the Board, and every other agency with a relatively broad delegation of

and *Capital Cities Cable*, however, implicitly contain at least one reasonable limitation on that power—it must be exercised expressly and specifically. Because of this requirement, federal agencies, which are not representative institutions, can be held at least somewhat accountable when they act to nullify state law.

The non-representative nature of federal regulatory agencies, as opposed to Congress, is a critical factor in setting appropriate standards for determining when preemption by regulation is appropriate. While the needs and interests of the state can perhaps be protected politically when the final decision is made by Congress, there is no similar political protection when fundamental decisions emanate from administrative agencies, which are generally intended to be relatively immune from direct political pressures in order to carry out Congress' will. Thus, the political relationship between Congress and the states created in the Constitution itself which the Court can rely upon to check *Congress'* excesses when it regulates matters traditionally subject to state and local government, *see Garcia v. San Antonio Metropolitan Transit Authority*, No. 82-1913 (Feb. 19, 1985), slip op. at 22, is completely missing when agencies are the source of preemptive decisionmaking authority. It is therefore necessary and appropriate for the Court to impose additional checks on agencies before holding that their regulatory actions can oust complementary state and local exercises of their police powers.

A rule requiring express preemption by agencies at least guarantees state and local officials an opportunity to engage the agency in a dialogue as to whether preemption of local law is in the public interest. Under the standard employed by the Eleventh Circuit, by contrast, federal agencies wishing to oust state authority would be able to enact a substantial number of minimum standards

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authority, has extraordinary power under *De La Cuesta* to nullify state law.

without mentioning in any notice to the public that the agency intends thereby to eliminate complementary state and local regulation. In this way, agencies could minimize the public comments, especially from state and local officials, that would otherwise be forthcoming if it were clear the agency intended to assert a particular power exclusively. This is no way to ensure responsible decision making by administrative agencies.

The Eleventh Circuit's rule also will encourage unnecessary litigation. Private interests currently being regulated by federal law will have a strong economic incentive to go to court to try to halt any local effort to impose any additional requirements on them. Under the vague standards adopted by the court of appeals for determining whether a federal agency has impliedly preempted state law, these private interests will very likely succeed, as appellees have here, in delaying the implementation of local laws designed to protect public health and safety.[16]

It is completely anomalous to have a rule for preemption that allows private parties to argue successfully that federal agencies, without even knowing it, have nullified state laws that are designed to protect the public health and welfare, which this Court has recognized "is a vital part of a state's police power." *Barsky v. Bd. of Regents*, 347 U.S. at 449. Probably no one was more surprised than FDA officials to learn that the agency's minimum

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[16] The court of appeals' implied preemption doctrine will almost certainly retard state and local efforts to adopt new public health and safety standards in areas that are presently subject to federal regulation. Not very many local jurisdictions will be willing to adopt standards and defend them all the way to this Court under the vague implied preemption standards employed by the court of appeals. This, of course, means that local experimentation with new standards will be curtailed and useful experience based on such standards will be lost. *See California v. Zook*, 336 U.S. 725, 737 (1949); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 310-311 (1932) (Brandeis, J., dissenting); *Anderson v. Dunn*, 6 Wheat. 204, 226 (1821).

standards had the effect of prohibiting all state and local efforts to adopt additional safety requirements for plasmapheresis to deal with special problems unique to a particular locality. Respect for state and local initiative demands that preemption not be the result of accident or misunderstanding.[17]

On the other hand, it is perfectly reasonable to require federal agencies to act responsibly and indicate clearly when and how they plan to exercise exclusive control over a particular subject. With the flexibility inherent in the notice and comment procedures, 5 U.S.C. § 553, agencies can notify the public about their plans, receive comments about the propriety of preemption and then carefully tailor the final regulations to protect areas that demand an exclusive federal presence.

Nor is it necessary for the Court to retain an implied preemption of the field doctrine for administrative agencies to deal with the issue posed by the "third test" in *Pennsylvania v. Nelson*, *viz.*, "whether the enforcement of state law presents a serious danger of conflict with the administration of the federal program." J.S. App. A10, citing, 350 U.S. at 505. Since agencies that have the authority to create minimum standards for an industry also will have the authority to preempt state law, they can respond specifically to any "serious dangers" that they

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[17] There is at least some risk that the implied preemption doctrine when applied to Congress' enactments would lead to similar problems, i.e., a court could find that Congress occupied the field even when Congress did not so intend. But the differences between Congress and administrative agencies make this problem much less likely when courts consider the preemptive effect of federal statutes. Congress ordinarily does not pass legislation that is so pervasive that it permits the clear inference that preemption was intended. Agencies, by contrast, almost always adopt exhaustive regulations. Moreover, it is much less reasonable to expect Congress to act with the same precision as an agency. By contrast, it is a relatively simple matter for a federal agency to adopt a regulation that clearly and expressly states what the agency intends to preempt.

perceive from state and local regulation on a case-by-case basis. If they do not perceive any danger to their program, it makes no sense for a federal court to find that one exists. Again, respect for state and local authority demands that agency preemption not be implied by federal courts, but rather be permitted only when the agency itself expresses a clear intent to preempt the field, which is accompanied by a factually-supported explanation of the clear need to oust non-conflicting state and local attempts to protect public health and safety.

In light of what we have argued, it is plain that the decision below must be reversed. The court of appeals itself held that neither Congress, expressly or implicitly, nor the FDA expressly preempted the field of plasmapheresis regulation. Since these are the only valid ways for federal law to preempt non-conflicting state law, the court of appeals erred in striking down the ordinances *completely* without considering whether the district court was correct in holding that there are no specific conflicts between the ordinances and the FDA's regulations (see pages 24-27, *infra*).

II. Implied Agency Preemption Should Be Permitted Only On The Basis Of A Clear Showing That State Or Local Law Conflicts With The Purpose Or Implementation Of The Federal Regulatory Scheme.

In its opinion, the court of appeals applied to agency regulation the three tests for preemption this Court discussed in *Pennsylvania v. Nelson*, for determining whether Congress *implicitly* preempted state law with respect to the criminal prosecution of subversives. J.S. App. A9-A10). First, the court of appeals asked whether the federal scheme is pervasive, and concluded it is because the FDA has a relatively extensive set of regulations concerning plasmapheresis. Second, the court asked whether the federal interest in the subject matter is so dominant that enforcement of state laws can be assumed to be inappropriate, and concluded it is because "blood is

an area of national concern." Third, the court asked whether enforcement of state law "presents a serious danger of conflict with the administration of the federal program," and concluded it does because the County's Ordinances might undermine the goal of maintaining a continued supply of healthy blood donors. (*Ibid.*).

The court of appeals erred, however, in its application of *Nelson* to federal *regulations*. The *Nelson* tests are simply not very meaningful when applied to federal agencies as opposed to Acts of Congress. While the first two tests are necessary in order to preempt state law impliedly, they clearly are not sufficient because they are likely to be satisfied by virtually any regulatory regime. The key *Nelson* factor which justifies *implying* preemption by agency regulations is whether state law actually conflicts with the purpose or implementation of the federal regulations. But even this standard must be applied carefully—implied preemption by regulation should occur only when the record clearly demonstrates a real conflict.

(A) The court of appeals erred initially in attaching any independent preemptive significance to the first two *Nelson* tests as they apply to agencies. First, the fact that an administrative agency has adopted "pervasive" regulations is hardly a basis for inferring preemptive intent.[18] As anyone who has ever perused the Code of Federal Regulations can attest, agency regulation by its nature tends to be fairly detailed in order to provide relatively clear guidance to regulated entities.

Indeed, this Court has held that, even when Congress itself treats a subject in exacting detail, an automatic inference of preemption is not waranted. *New York Dep't. of Social Services v. Dublino*, 413 U.S. at 415. As the Court explained "[g]iven the complexity of the matter addressed by Congress in the federal work incentive

[18] Obviously, the absence of a pervasive scheme is powerful evidence that an agency did not intend impliedly to oust complementary state and local law.

program, a detailed statutory scheme was both likely and appropriate, completely apart from any question of preemptive intent." *Ibid.*; *see De Canas v. Bica*, 424 U.S. at 359.

It would grossly distort the preemption doctrine, which presumes that state laws are valid unless federal law clearly requires otherwise,[19] to hold that simply because an agency has adopted a substantial number of detailed regulations concerning a subject, that area is rendered off limits to complementary state and local law designed to protect the public health and safety. Under the reasoning of the court below, whenever a federal agency enacted comprehensive minimum standards for an industry, it would have to declare expressly that it did *not* intend its regulations to be exclusive in order to eliminate the inference of preemptive intent that the court of appeals found here.

The second *Nelson* factor, whether the subject is a matter of "dominant" national concern, is also an inappropriate measure of implied regulatory preemption. It is inconceivable that any subject that Congress itself does not regard as a matter of dominant national concern can become such solely by virtue of how the agency regulates it. Certainly, this is not such a case.

The court of appeals relied largely on administrative statements indicating that the supply of blood is a matter not of "dominant" national concern, but only of "national concern." But the fact that a federal agency has promulgated regulations pursuant to a federal statute means that the subject matter is per se of concern to the federal government. Moreover, it will be the unusual case when a litigant cannot cite broad language in the Federal Register explaining that the subject of

[19] *See, e.g., Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 445 (1960); *Schwartz v. Texas*, 344 U.S. 199, 202-203 (1952); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

the regulation and the need for some minimum standards is a matter of national concern. Otherwise, there would be no point in proposing regulations. To imply preemption of the field from such statements would therefore unduly expand areas of preemption. There are a host of subjects that are proper concerns of the federal government that are equally appropriate for local complementary regulations; but the second *Nelson* test wholly fails to recognize any of them.

(B) The crucial issue in determining implied preemption by federal regulation must be the third *Nelson* test—whether the state and local regulations conflict with the purpose or implementation of the federal regulatory regime. *See Michigan Canners & Freezers Ass'n. v. Agricultural Marketing and Bargaining Bd.*, —— U.S. ——, 104 S. Ct. 2518 (1984); *Campbell v. Hussey*, 368 U.S. 297, 301 (1961). The court of appeals did find a conflict between the two schemes, but its cavalier handling of this issue without any serious analysis of the "conflict" is completely inadequate. Principles of federalism require the Court to uphold the County's exercise of its police power unless there is an inevitable clash between the County's purpose and the FDA's or if the obligations imposed by the County create conflicting duties or otherwise impair implementation of the agency's regulatory mission. But in this case the purposes of the two schemes are completely compatible and the County imposes no obligation on anyone that will interfere with the FDA's ability to regulate plasmapheresis centers under its regulations. We will analyze the relationship between the purposes first and then discuss the effect of the County's scheme on the implementation of the federal program.

(1) The FDA's regulations expressly state that they are intended only to protect the vendor's health and safety and to assure a supply of pure blood plasma. *See* page 3, *supra*. These goals are fully consistent with the goals of the County's Ordinances. *See* page 6, *supra*. All the County's Ordinances do is fill a serious void in the federal regulatory protections and thereby better assure that the donors' safety is protected and that each donor supplies a safe quality and quantity of blood plasma in order to protect the employees of the plasmapheresis centers. It should be the rare case when a state program is declared invalid when it has not merely complementary goals, but goals that are virtually identical to the federal administrative scheme. *See Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 132 (1978); *California v. Zook*, 336 U.S. at 737.[20]

The court of appeals asserts, without any real evidence, that the County's ordinances will adversely affect the national goal of "guaranteeing a continued supply of healthy donors. . . ." (J.S. App. A11). This is the only finding of a conflict between federal and local goals that even arguably supports implied preemption. But the court of appeals made no effort to explain how these Ordinances could possibly limit the supply of healthy donors. They might limit the supply of *unhealthy* donors, but that is fully consistent with the purposes of the FDA's regulations. Certainly, principles of comity between the federal government and state and local governments require a court to provide a clearer explanation based on a fuller factual foundation of how the purposes of local laws con-

[20] The court of appeals assumes from the existence of minimum standards in the FDA's regulations that these standards were intended to be exclusive. But the goal of uniformity in minimum standards is weak, if any, evidence of a federal purpose to set exclusive standards. Simply because the FDA has concluded that it should enact certain minimum requirements nationwide to protect donor safety does not mean that the FDA intended to protect the plasmapheresis centers from any additional burdens imposed by local officials that are intended to further aims that are identical to the FDA's program. Thus, whether the County's ordinances undermine "uniformity" is, in and of itself, no basis for concluding that the ordinance poses a real danger to the underlying *federal objective*, which is protecting safety and health. *See Florida Lime & Avocado Growers, Inc. v. Paul, supra*, 373 U.S. at 147-148.

flict with the purposes of federal law than the court of appeals has offered here, before state and local attempts to provide non-conflicting standards to protect public health and safety can be nullified. *Huron Portland Cement Co. v. Detroit*, 362 U.S. at 446.[21]

(2) Nor is there any basis for concluding that the federal and county programs clash in a way that will interfere with the FDA's implementation of its regulations. Of course, if a County requirement actually conflicted with an FDA regulation, then it would be preempted. But there are no conflicts in this case.

To the extent the two regulatory schemes overlap, the County imposes somewhat greater obligations on the plasmapheresis centers than does the FDA. See pages 6-7, *supra*. But it is certainly possible for the centers to comply with both laws. Similarly, the County imposes an additional obligation on the donors, but requiring identification cards and a breathalyzer test does not conflict with the FDA's regulations in any way that would render it impossible for the underlying purposes of federal law to be achieved fully.[22] These matters are simply not addressed by federal law. Compare *Exxon Corp. v. Governor of Maryland*, 437 U.S. at 131. Finally, the County will provide an additional set of inspections,

[21] It is not at all clear precisely how the court of appeals believes that the County's standards will undermine the goal of guaranteeing a supply of healthy donors. To the extent that the court was concerned about the basic viability of the plasmapheresis centers, its conclusion is unsupported by the findings of the district court, which concluded that appellee's assertion of financial harm caused by the Ordinances was too speculative to be credited (J.S. App. A15-A16). The court of appeals did not even address this finding much less hold that it was clearly erroneous. Moreover, it is not the purpose of the FDA's regulations to protect plasmapheresis centers from the ordinary expenses of doing business within a particular locality.

[22] *See Hines v. Davidowitz*, 312 U.S. at 67-68; *Jones v. Rath Packing Co.*, 430 U.S. at 526, 540-541; *De Canas v. Bica*, 424 U.S. at 363.

but there is no reason to assume without evidentiary support that the County would interfere in any way with the FDA's enforcement efforts. Both sets of regulations therefore can co-exist in harmony, and accordingly, the court of appeals erred in holding the County's Ordinances unconstitutional under the Supremacy Clause.[23]

[23] The Solicitor General in his *amicus* brief at the jurisdictional stage of this case suggested (Br. at 10-12) that the Ordinance's "Certificate of Good Health" requirement for all vendors may conflict with a special FDA regulation that allows some donors who are hepatitis-reactive to sell blood for the purpose of manufacturing the vaccine used to prevent hepatitis. *See* 21 C.F.R. 610.41, 640.75. But there is no reason for this Court to speculate about this issue in this appeal. It is clear that appellee's plasmapheresis center is not a specialized facility licensed by the FDA under 21 C.F.R. 640.75, to accept blood from hepatitis-reactive donors. As the court of appeals explained, "[t]he staff physician rejects any candidate who has a history of viral hepatitis" and appellee's center "destroys the unit of plasma" if it is contaminated. J.S. App. A4. Thus, appellee has no standing to complain about the effect of the "Certificate of Good Health" requirement as it might apply to a different type of center.

Moreover, it is hardly clear that Ordinance #80-12 was intended to preclude specialized plasmapheresis centers from operating within the County. The Ordinance expressly incorporates 21 C.F.R. 640.75, as one of the provisions of the FDA regulations that the County will enforce. *See* Ordinance #80-12, § 15; J.S. App. A38-A39 (incorporating Section 640 *et seq.* of FDA's regulations). That is the provision that allows the FDA to license special facilities. Since the County has authorized such facilities, it would seem quite unlikely that it would interpret its Ordinance so as not to allow anyone to donate blood to them. Under these circumstances, for the Court to strike down the County's "Certificate of Good Health" requirement as applied "would be to ignore the teaching of this Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists." *Huron Portland Cement Co. v. Detroit*, 362 U.S. at 446.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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